Substitute Form PTO-1449 (Modified)

U.S. Department of Commerce Patent and Trademark Office Attorney's Docket No. 17023-035001

Application No. 10/718,262

JAN 0 6 2005

Information Disclosure Statement by Applicant (Use several sheets if necessary) Applicant

Paul B. McCrary, Jr. et al.

Filing Date

November 20, 2003

Group Art Unit 1636

| ıD, | Z | | | | | | | |
|-----|----------|--------|-----------|-------------|-------------------|---------------------|---|----------------|
| | | | | U.S. Pate | nt Documents | | | |
| Ī | Examiner | Desig. | Document | Publication | | | | Filing Date |
| Į | Initial | 1D | Number | Date | Patentee | Class | Subclass | If Appropriate |
| | 02. | AA | 5,512,421 | 04/30/96 | Burns et al. | \mathbb{N} | $\langle \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \$ | |
| | d | AB | 5,643,756 | 07/01/97 | Kayman et al. | X/ | | . 6 |
| | 81 | AC | 5,654,195 | 08/05/97 | Sodroski et al. | | | |
| ſ | 91 | AD | 5,670,354 | 09/23/97 | Burns et al. | $\langle X \rangle$ | (X) | |
| | 27 | ΑE | 5,693,509 | 12/02/97 | Cotten et al. | | \bigvee | • |
| | N | AF | 5,711,964 | 01/27/98 | Dattagupta et al. | | $\bigwedge \bigwedge$ | N. |
| | y | AG | 5,739,271 | 04/14/98 | Sridhar et al. | $X \rightarrow$ | $(X \)$ | |
| | N | АН | 6,440,730 | 08/27/02 | Von Laer et al. | | | • |
| | N. | AI | 6,531,123 | 03/11/03 | Chang | | | |
| | OZ | AJ | 6,589,763 | 07/08/03 | Von Laer et al. | V. / | $(X\Lambda)$ | |

| Foreign Patent Documents or Published Foreign Patent Applications | | | | | | | | |
|---|--------|-------------|-------------|---------------|-------|----------|-------|---------|
| Examiner | Desig. | Document | Publication | Country or | | | Trans | slation |
| Initial | ID | Number | Date | Patent Office | Class | Subclass | Yes | No |
| il | AK | WO 98/44788 | 10/15/98 | PCT . | | | | |

| | Other Documents (include Author, Title, Date, and Place of Publication) | | | | |
|---|---|---|--|--|--|
| Examiner Initial | Desig. ID | Document | | | |
| 97 | AL | GenBank Accession No. V00878 dated 02/25/03 | | | |
| Altschul et al., "Gapped BLAST and PSI-BLAST: a new generation of protein database search programs," Nucl. Acids. Res., 1997, 25 (17):3389-3402 | | | | | |
| 07 | AN | Altschul et al., "Basic Local Alignment Search Tool," J. Mol. Biol., 1990, 215:403-410 | | | |
| 91 | AO | Alvarez-Buylla et al., "Identification of neural stem cells in the adult vertebrate brain," Brain Res. Bull., 2002, 57(6):751-758 | | | |
| 01 | AP | Beyer et al., "Oncoretrovirus and Lentivirus Vectors Pseudotyped with Lymphocytic Choriomeningitis Virus Glycoprotein: Generation, Concentration, and Broad Host Range," <u>J. Virol.</u> , 2002, 76(3):1488-1495 | | | |
| 91 | AQ | Beyer et al., "Recombinant Expression of Lymphocytic Choriomeningitis Virus Strain WE Glycoproteins: a Single Amino Acid Makes the Difference," J. Virol., 2001, 75(2):1061-1064 | | | |
| AR Boshart et al., "A Very Strong Enhancer Is Located Upstream of an Immediate Early Gene of Human Cytomegalovirus," Cell, 1985, 41:521-530 | | | | | |
| 02 | AS | Buchmeier et al., "Arenaviridae: The Viruses and Their Replication," Fields Virology, 4th ed., 2001, Knipe and Howley (eds.), Lippincott Williams & Wilkins, Vol. 2, pp. 1635-1668 | | | |

| Examiner Signature David June | Date Considered |
|---|---|
| EXAMINER: Initials citation considered. Draw line through citation if no next communication to applicant. | t in conformance and not considered. Include copy of this form with |

| Substitute Form PTO-1449 | U.S. Department of Commerce Patent and Trademark Office | Attorney's Docket No. 17023-035001 | Application No. 10/718,262 |
|--------------------------|--|---|----------------------------|
| | closure Statement | Applicant Paul B. McCrary, Jr. et al. | |
| | neets if necessary) | Filing Date Group Art Unit November 20, 2003 1636 | |

| | | ocuments (include Author, Title, Date, and Place of Publication) | | |
|---------------------|---|---|--|--|
| Examiner Initial | Desig. ID | Document | | |
| THU CH | | Burns et al., "Vesicular stomatitis virus G glycoprotein pseudotyped retroviral vectors: | | |
| 22 | AT | Concentration to very high titer and efficient gene transfer into mammalian and nonmammalian cells," Proc. Natl. Acad. Sci. USA, 1993, 90:8033-8037 | | |
| 01 | AU | Cao et al., "Identification of α-Dystroglycan as a Receptor for Lymphocytic Choriomeningitis Virus and Lassa Fever Virus," Science, 1998, 282:2079-2081 | | |
| 87 | AV | Chang et al., "Human Immunodeficiency Viruses Containing Heterologous Enhancer/Promoters Are Replication Competent and Exhibit Different Lymphocyte Tropisms," J. Virol., 1993, 67:743-752 | | |
| 0 | AW | Chen et al., "Generation of packaging cell lines for pseudotyped retroviral vectors of the G protein of vesicular stomatitis virus by using a modified tetracycline inducible system," <u>Proc. Natl. Acad. Sci. USA</u> , 1996, 93:10057-10062 | | |
| 01 | AX | Corpet et al., "Multiple sequence alignment with hierarchical clustering," Nucl. Acids. Res., 1988, 16:10881-10891 | | |
| 07 | AY | Culver et al., "Lymphocyte Gene Therapy," Human Gene Ther., 1991, 2(2):107-109 | | |
| 07 | AZ | DePolo et al., "VSV-G Pseudotyped Lentiviral Vector Particles Produced in Human Cells Are Inactivated by Human Serum," Mol. Ther., 2000, 2:218-222 | | |
| 67 | AAA | Dijkema et al., "Cloning and expression of the chromosomal immune interferon gene of the rat," EMBO J., 1985, 4(3):761-767 | | |
| 0 | ABB | Doetsch et al., "Subventricular Zone Astrocytes Are Neural Stem Cells in the Adult Mammalian Brain," Cell, 1999, 97(6):703-716 | | |
| 07 | ACC | Doetsch et al., "Regeneration of a germinal layer in the adult mammalian brain," <u>Proc. Natl. Acad. Sci. USA</u> , 1999, 96(20):11619-11624 | | |
| 97 | ADD | Duisit et al., "Five Recombinant Simian Immunodeficiency Virus Pseudotypes Lead to Exclusiv Transduction of Retinal Pigmented Epithelium in Rat," Mol. Ther., 2002, 6(4):446-454 | | |
| 01 | AEE | Gewirtz, "Oligodeoxynucleotide-Based Therapeutics for Human Leukemias," <u>Stem Cells</u> , 1993, 11(Suppl. 3):96-103 | | |
| 01 | AFF | Goff, "Intracellular trafficking of retroviral genomes during the early phase of infection: viral exploitation of cellular pathways," <u>J. Gene Med.</u> , 2001, 3:517-528 | | |
| 01 | AGG | Gorman et al., "The Rous sarcoma virus long terminal repeat is a strong promoter when introduced into a variety of eukaryotic cells by DNA-mediated transfection," <u>Proc. Natl. Acad. Sci. USA</u> , 1982, 79:6777-6781 | | |
| H | AHH Grossman et al., "Successful ex vivo gene therapy directed to liver in a patient with familiar hypercholesterolaemia," Nat. Genet., 1994, 6:335-341 | | | |
| 91 | AII | Henry and Campbell, "A Role for Dystroglycan in Basement Membrane Assembly," Cell, 1998, 95:859-870 | | |
| 97 | AJJ | Henry and Campbell, "Dystroglycan inside and out," Curr. Opin. Cell Biol., 1999, 11:602-607 | | |
| 91 | AKK | Higgins and Sharp, "Fast and sensitive multiple sequence alignments on a microcomputer," CABIOS, 1989, 5(2):151-153 | | |
| 91 | ALL | Higgins et al., "CLUSTAL: a package for performing multiple sequence alignment on a microcomputer," Gene, 1988, 73:237-244 | | |
| 19 | AMM | Huang et al., "Parallelization of a local similarity algorithm," CABIOS, 1992, 8(2):155-165 | | |
| 91 | ANN | Johnston et al., "Minimum Requirements for Efficient Transduction of Dividing and Nondividing Cells by Feline Immunodeficiency Virus Vectors," J. Virol., 1999, 73(6):4991-5000 | | |
| xaminer Sign | ature | Date Considered | | |

| Examiner Signature | Date Considered |
|--|--|
| Examiner Signature . | Date Considered |
| | 1 / / / |
| Lawy Lung | 10/26/05 |
| | |
| EXAMINER: Initials citation considered. Draw line through citation if no | at in conformance and not considered. Include copy of this form with |
| next communication to applicant | |

| Substitute Form PTO-1449 (Modified) | U.S. Department of Commerce Patent and Trademark Office | Attorney's Docket No. 17023-035001 | Application No. 10/718,262 |
|---|--|---------------------------------------|----------------------------|
| | closure Statement | Applicant Paul B. McCrary, Jr. et al. | |
| (Use several sheets if necessary) (37 CFR §1.98(b)) | | Filing Date November 20, 2003 | Group Art Unit 1636 |

| | Other D | ocuments (include Author, Title, Date, and Place of Publication) |
|---|----------|--|
| Examiner | Desig. | Degument |
| Initial | ID | Document Kang et al., "In Vivo Gene Transfer Using a Nonprimate Lentiviral Vector Pseudotyped with Ross |
| 20 | A00 | River Virus Glycoproteins," J. Virol., 2002, 76(18):9378-9388 |
| Karlin and Altschul, "Methods for assessing the stati | | Karlin and Altschul, "Methods for assessing the statistical significance of molecular sequence features by using general scoring schemes," Proc. Natl. Acad. Sci. USA, 1990, 87:2264-2268 |
| 01 | AQQ | Karlin and Altschul, "Applications and statistics for multiple high-scoring segments in molecular sequences," Proc. Natl. Acad. Sci. USA, 1993, 90:5873-5877 |
| 01 | ARR | Kasid et al., "Human gene transfer: Characterization of human tumor-infiltrating lymphocytes as vehicles for retroviral-mediated gene transfer in man," Proc. Natl. Acad. Sci. USA, 1990, 87:473-477 |
| 91 | ASS | Kenyon et al., "Aerosol Infection of Rhesus Macaques with Junin Virus," Intervirology, 1992, 33:23-31 |
| 97 | ATT | Kim et al., "Use of the human elongation factor 1α promoter as a versatile and efficient expression system," Gene, 1990, 91:217-223 |
| 61 | AUU | Lehninger, "The amino acid building blocks of proteins," <u>Biochemistry</u> , 2 nd edition, 1975, The Johns Hopkins University School of Medicine, pp. 73-75 |
| 19 | AVV | Lever, "HIV and other lentivirus-based vectors," Gene Therapy, 1996, 3:470-471 |
| 9 | AWW | Maniatis et al., "Regulation of Inducible and Tissue-Specific Gene Expression," Science, 1987, 236:1237-1245 |
| 91 | AXX | Mann et al., "Construction of a Retrovirus Packaging Mutant and Its Use to Produce Helper-Free Defective Retrovirus," Cell, 1983, 33:153-159 |
| 91 | AYY | Markowitz et al., "A Safe Packaging Line for Gene Transfer: Separating Viral Genes on Two Different Plasmids," J. Virol., 1988, 62(4):1120-1124 |
| . 91 | AZZ | Meinkoth and Wahl, "Hybridization of Nucleic Acids Immobilized on Solid Supports," Anal. Biochem., 1984, 138:267-284 |
| 01 | AAAA | Miletic et al., "Retroviral Vectors Pseudotyped with Lymphocytic Choriomeningitis Virus," <u>J. Virol.</u> , 1999, 73(7):6114-6116 |
| 91 | ABBB | Miller, "Human gene therapy comes of age," Nature, 1992, 357:455-460 |
| H | ACCC | Miller, "Cell-surface receptors for retroviruses and implications for gene transfer," Proc. Natl. Acad. Sci. USA, 1996, 93:11407-11413 |
| 7 | ADDD | Mizushima and Nagata, "pEF-BOS, a powerful mammalian expression vector," Nucl. Acids Res., 1990, 18(17):5322 |
| 91 . | AEEE | Myers and Miller, "Optimal alignments in linear space," CABIOS, 1988, 4(1):11-17 |
| 01 | AFFF | Neckers and Whitesell, "Antisense technology: biological utility and practical considerations," Amer. J. Physiol., 1993, 265:L1-L12 |
| 91 | AGGG | Needleman and Wunsch, "A General Method Applicable to the Search for Similarities in the Amino Acid Sequence of Two Proteins," J. Mol. Biol., 1970, 48:443-453 |
| M | АННН | Park et al., "Therapeutic levels of human factor VIII and IX using HIV-1-based lentiviral vectors in mouse liver," <u>Blood</u> , 2000, 96(3):1173-1176 |
| ol | AIII | Pearson and Lipman, "Improved tools for biological sequence comparison," Proc. Natl. Acad. Sci. USA, 1988, 85:2444-2448 |
| W | AJJJ | Pearson et al., "Using the FASTA Program to Search Protein and DNA Sequence Databases," Meth. Mol. Biol., 1994, 24:307-331 |
| Examiner Sign | nature / | Date Considered , |

| Examiner Signature and June | /0/26/05 |
|--|---|
| EXAMINER: Initials citation considered. Draw-line through citation if no | t in conformance and hot considered. Include copy of this form with |
| next communication to applicant. | |
| | Substitute Disclosure Form (PTO-1449) |

| Substitute Form PTO-1449 (Modified) | U.S. Department of Commerce Patent and Trademark Office | | Application No. 10/718,262 |
|-------------------------------------|--|---------------------------------------|----------------------------|
| (Use several sheets if necessary) | | Applicant Paul B. McCrary, Jr. et al. | |
| | | Filing Date November 20, 2003 | Group Art Unit 1636 |

| Other Documents (include Author, Title, Date, and Place of Publication) | | | |
|---|--------------|--|--|
| Examiner Initial | Desig. ID | Document | |
| 07 | AKKK | Rosenberg, "Human Gene Marker/Therapy Clinical Protocols," <u>Human Gene Therapy</u> , 1994, 5(1):140 | |
| 07 | ALLL | Russell and Miller, "Foamy Virus Vectors," J. Virol., 1996, 70(1):217-222 | |
| , 91 | AMMM | derived from human and nonhuman primates," Blood, 2002, 100(3):823-832 | |
| 01 | ANNN | Schauber et al., "Lentiviral vectors pseudotyped with baculovirus gp64 efficiently transduce mouse cells in vivo and show tropism restriction against hematopoietic cell types in vitro," Gene Ther., 2004, 11:266-275 | |
| 01 | A000 | Schwartz et al., "Distinct RNA Sequences in the gag Region of Human Immunodeficiency Virus Type 1 Decrease RNA Stability and Inhibit Expression in the Absence of Rev Protein," J. Virol., 1992, 66(1):150-159 | |
| 07 | APPP | Sinn et al., "Lentivirus Vectors Pseudotyped with Filoviral Envelope Glycoproteins Transduce Airway Epithelia from the Apical Surface Independently of Folate Receptor Alpha," <u>J. Virol.</u> , 2003, 77(10):5902-5910 | |
| 87 | AQQQ | Smith and Waterman, "Comparison of Biosequences," Adv. Appl. Math., 1981, 2:482-489 | |
| 91 | ARRR | Spiropoulou et al., "New World Arenavirus Clade C, but Not Clade A and B Viruses, Utilizes α-Dystroglycan as Its Major Receptor," J. Virol., 2002, 76(10):5140-5146 | |
| 91 | ASSS | Steffy and Wong-Staal, "Genetic Regulation of Human Immunodeficiency Virus," Microbiol. Rev., 1991, 55:193-205 | |
| 97 | ATTT | Stein et al., "In Vivo Treatment of Hemophilia A and Mucopolysaccharidosis Type VII Using Nonprimate Lentiviral Vectors," Mol. Ther., 2001, 3:850-856 | |
| 01 | AUUU | Stewart et al., "Lentiviral delivery of HIV-1 Vpr protein induces apoptosis in transformed cells," <u>Proc. Natl. Acad. Sci. USA</u> , 1999, 96(21):12039-12043 | |
| . 91 | AVVV | Stryer, "Conformation and Dynamics," <u>Biochemistry</u> , 2 nd edition, 1981, W.H. Freeman and Co., San Francisco, pp. 14-15 | |
| 91 | AWWW | Subbramanian and Cohen, "Molecular Biology of the Human Immunodeficiency Virus Accessory Proteins," J. Virol., 1994, 68(11):6831-6835 | |
| . 91 | AXXX | Talbott et al., "Nucleotide sequence and genomic organization of feline immunodeficiency virus," <u>Proc. Natl. Acad. Sci. USA</u> , 1989, 86:5743-5747 | |
| 01 | AYYY | Trono et al., "HIV Accessory Proteins: Leading Roles for the Supporting Cast," Cell, 1995, 82:189-192 | |
| A | AZZZ | Uetsuki et al., "Isolation and Characterization of the Human Chromosomal Gene for Polypeptide Chain Elongation Factor-1α," J. Biol. Chem., 1989, 264:5791-5798 | |
| H | AAAAA | Voss et al., "The role of enhancers in the regulation of cell-type-specific transcriptional control," <u>Trends Biochem. Sci.</u> , 1986, 11:287-289 | |
| 91 | ABBBB | Wang et al., "Feline immunodeficiency virus vectors persistently transduce nondividing airway epithelia and correct the cystic fibrosis defect," J. Clin. Invest., 1999, 104:R55-62 | |
| Z | ACCCC | Watson et al., "Targeted Transduction Patterns in the Mouse Brain by Lentivirus Vectors | |

| Examiner Signature | Date Considered |
|--|---|
| EXAMINER: Initials citation considered. Draw line through citation if no next communication to applicant | t in conformance and not considered. Include copy of this form with |

| Substitute Form PTO-1449 (Modified) | U.S. Department of Commerce Patent and Trademark Office | Attorney's Docket No. 17023-035001 | Application No. 10/718,262 |
|--|--|---------------------------------------|----------------------------|
| Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b)) | | Applicant Paul B. McCrary, Jr. et al. | |
| | | Filing Date November 20, 2003 | Group Art Unit 1636 |

| Other Documents (include Author, Title, Date, and Place of Publication) | | |
|---|--------------|--|
| Examiner Initial | Desig. ID | Document |
| 07 | ADDDD | White et al., "Airway Epithelial Cell Wound Repair Mediated by & Dystroglycan," Am. J. Respir. Cell Mol. Biol., 2001, 24:179-186 |
| Ol | AEEEE | Yamada et al., "Nanoparticles for the delivery of genes and drugs to human hepatocytes," Nature Biotechnology, 2003, 21(8):885-890 |

Date Considered Examiner Signature EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.